



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER OF PATENTS AND TRADEMARKS  
Washington, D.C. 20231  
[www.uspto.gov](http://www.uspto.gov)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/597,738	06/19/2000	H. William Bosch	029318/0615	3886

7590 03/13/2002

Foley & Lardner  
Washington Harbor  
Suite 500  
3000 K Street NW  
Washington, DC 20007-5109

[REDACTED] EXAMINER

BAWA, RAJ

[REDACTED] ART UNIT

[REDACTED] PAPER NUMBER

1616

DATE MAILED: 03/13/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

\* Restart 4/29/02 due to both copies  
of action was still inside of file

B. Shay  
4-26-02

<b>Office Action Summary</b>	Application No. <b>09/597,738</b>	Applicant(s) <b>Bosch</b>
	Examiner <b>Bawa</b>	Art Unit <b>1616</b>

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1)  Responsive to communication(s) filed on Nov 14, 2001.
- 2a)  This action is FINAL.      2b)  This action is non-final.
- 3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

#### Disposition of Claims

- 4)  Claim(s) 51-117 is/are pending in the application.
- 4a) Of the above, claim(s) 65-78, 82, 83, and 102-117 is/are withdrawn from consideration.
- 5)  Claim(s) \_\_\_\_\_ is/are allowed.
- 6)  Claim(s) 51-64, 79-81, and 84-101 is/are rejected.
- 7)  Claim(s) \_\_\_\_\_ is/are objected to.
- 8)  Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9)  The specification is objected to by the Examiner.
- 10)  The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11)  The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved.
- 12)  The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. § 119

- 13)  Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) All b) Some\* c) None of:
1.  Certified copies of the priority documents have been received.
  2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

- 14)  Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

#### Attachment(s)

- 15)  Notice of References Cited (PTO-892)      18)  Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 16)  Notice of Draftsperson's Patent Drawing Review (PTO-948)      19)  Notice of Informal Patent Application (PTO-152)
- 17)  Information Disclosure Statement(s) (PTO-1449) Paper No(s). 4, 6, 9      20)  Other: \_\_\_\_\_

### Detailed Action

1. Applicant's election with traverse of claims 51-64, 79-81 and 84-101 in Paper No. 8 is acknowledged. The traversal is on the ground(s) that there would be no serious burden on the PTO to examine both groups of claims. This is not found persuasive because the two distinct set of claims are classified separately and have acquired a separate status in the art. Clearly , they are directed towards divergent subject matter.

The requirement is still deemed proper and is therefore made FINAL.

Cancellation of all non-elected claims is requested to enhances prosecution.

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 51-64, 79-81 and 84-101are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

(i) The term "essentially" is vague in the context employed. It is unclear whether it refers to each and every droplet or a few.

(ii) It is unclear as to what is referred to by "therapies" (e.g., claim 52) since the Markush group refers to a "drug" per se.

(iii) The phrase "poorly soluble" is vague and indefinite since it does not specify the medium (water, oil, etc.) with which the solubility is gauged. As a result, the metes and bounds of the patent protection desired <sup>are</sup> ~~are~~ unascertainable.

(iv) Please replace PMDI and non-CFC with their full terms.

Art Unit: 1616

In view of the above statements, it is the Examiner's position that the claims do not meet the threshold requirement of clarity and precision and are not in compliance for definiteness of 35 U.S.C. 112, second paragraph. Note that definiteness of the claims is important to allow others who wish to enter the marketplace to ascertain the boundaries of protection that are provided by the claims (Ex parte Kristensen 10 USPQ2d 1701, 1703).

3. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Raj Bawa whose telephone number is 308-2423. The examiner can normally be reached on Tuesday to Friday from 7:30 AM to 6 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose Dees, can be reached on (703) 308-4628. The fax phone number for the organization where this application or proceeding is assigned is 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 308-1235.

Bawa/LR

March 6, 2002



RAJ BAWA, Ph.D.  
PRIMARY EXAMINER